I. Claims 20-39 and 42, drawn to a method of potentiating an immune response in a human comprising administering an antigen and an effective amount of an adjuvant comprising papaya mosaic virus (PMSV), or a PMSV virus-like particle, classified in class 435, subclass 235.1.

II. Claims 20-38 and 40, drawn to a method of potentiating an immune response in a bird comprising administering an antigen and an effective amount of an adjuvant comprising PMSV, or a PMSV virus-like particle, classified in class 435, subclass 235.1.

III. Claims 20-38 and 41, drawn to a method of potentiating an immune response in a fish comprising administering an antigen and an effective amount of an adjuvant comprising PMSV, or a PMSV virus-like particle, classified in class 435, subclass 235.1.

The Examiner alleged that Inventions I-III are unrelated because the inventions are not disclosed as useable together as they are drawn to methods for inducing an immune response in different groups of vertebrates. The Examiner further alleged that this difference provides the inventions different modes of operation and different functions. The Examiner alleged that the inventions have different modes of operation because they are administered to different populations, while the objective of treating these populations gives the methods different functions.

Applicants respectfully traverse the above restriction for the following reasons. The currently pending claims are directed to methods of potentiating an immune response against an antigen using a specifically defined adjuvant. Dependent claims further define the claimed subject matter, varying in breadth or scope of definition. As such, Applicants assert that the currently pending claims relate to the same embodiment of the invention, *i.e.* a method of potentiating an immune response against an antigen, and define the same essential characteristics of this embodiment, namely administration of an antigen in combination with a specifically defined adjuvant. Accordingly, Applicants assert that restriction of the currently pending claims should not be required (*see*, MPEP § 806.03).

Furthermore, Applicants assert that the methods of the pending claims all have the same mode of operation, the same function and the same effects. Contrary to the Examiner's assertion, regardless of the animal population, the instantly claimed methods all have the same mode of operation, *i.e.* administration of an antigen in combination with a specifically defined adjuvant, for which similar materials and methodologies can be utilized. Similarly, regardless of the target animal population, the methods of currently pending claims all have the same objective, namely, to potentiate an immune response to the antigen in the animal and, therefore, all have the same function. Moreover, regardless of the animal population, the claimed methods will all result in same end effect: the potentiation of an immune response in the animal against the administered antigen. Accordingly, Applicants assert that the currently pending claims are in fact directed to a single invention and do not meet the definition of independent inventions as set forth in MPEP 806.04 and relied upon by the Examiner.

Moreover, MPEP § 803 clearly states there are **two** criteria that must be met for a proper requirement for restriction between patentably distinct inventions: (A) the inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i)); **and** (B) there must be a serious burden on the Examiner if restriction is required (see MPEP § 803.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02)[emphasis added]. If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

For the reasons set forth above, Applicants maintain that the currently pending claims do not represent independent or distinct inventions, but rather all relate to the same general inventive concept (*i.e.* methods of potentiating an immune response by administering an antigen in combination with a specifically defined adjuvant). As such, a search of the prior art with respect to this common inventive concept can be easily conducted and does not represent any serious

burden on the Examiner. In addition, it is known in the art that a single infectious agent can infect a variety of different species and, for this reason, animal models are frequently utilized in the art to determine the ability of an antigen to potentiate an immune response against a human pathogen. Applicants therefore assert that in order to perform a thorough search of claims directed to a method of potentiating an immune response to an antigen in any one group of animals, methods of potentiating an immune response to the same antigen in other groups of animals must also be searched. As such, searching and examining all the currently pending claims in a single application does not constitute any additional burden on the Examiner. Accordingly, Applicants assert that the Examiner has failed to meet both criteria set out in MPEP § 803 for proper restriction and that all the currently pending claims should, therefore, be searched and examined in the instant application.

Applicants also note that the Examiner has defined alleged Invention I (claims 20-39 and 42) as being drawn to a method of potentiating an immune response in a human. However, the instant specification and currently pending claims clearly contemplate that the methods are applicable to all mammals, see for example, paragraph [0021] of the instant specification and currently pending claim 39, which clearly recites "The method of claim 38, wherein said animal is a mammal" [emphasis added]. As would be readily appreciated by the skilled worker, materials and methodologies utilized to potentiate an immune response against an antigen in humans and other mammals are highly analogous. Accordingly, whether the target animal is a human or a non-human mammal, the mode of operation, function, and end effect of the instantly claimed methods are the same. Accordingly, Applicants assert that alleged Invention I should be defined as related to a method of potentiating an immune response in a mammal comprising administering an antigen and an effective amount of an adjuvant comprising papaya mosaic virus (PapMV), or a PapMV virus-like particle, and thus should encompass claims directed to methods of potentiating an immune response in both humans and other mammals.

The Examiner has further alleged that the application contains claims directed to the following patentably distinct species of antigen:

i. Viral antigen
ii. Bacterial antigen
iii. Parasitic antigen

The Examiner alleged that these species are unrelated because they are not disclosed as useable together. The Examiner alleged that this results because the species are used to potentiate an immune response against different pathogens and this difference also gives the Species i-iii different functions.

Applicants respectfully traverse the Examiner's objection. Contrary to the Examiner's allegation, the instant specification discloses that a variety of antigens may be used together in the methods of the currently pending claims. For example, the specification as originally filed clearly indicates that the immunogen-carrier complex may comprise more than one immunogen and may have more than one specificity, see paragraph [0013] of the instant specification which states that "[o]ne aim of the present invention is to provide an immunogen-carrier complex...consisting of a viral-like particle (VLP) carrying at least one immunogen..." [emphasis added] and paragraph [0051] which states "...one or more forms of an immunogen are coupled to one or more carrier VLPs and a plurality of such complexes is administered" [emphasis added]. As indicated at paragraph [0050] of the specification as originally filed these immunogens may be viral, bacterial or parasitical (see also, claim 4, as originally filed). Moreover, Applicants assert that the use of multivalent vaccines to immunize against multiple diseases is well known in the art (see, for example paragraph [0011], first line] and the specification as filed also discloses the use of such multivalent vaccines. For example, paragraph [0048] states "...there are provided certain novel immunogen-carriers...which are useful in providing univalent as well as multivalent immunogenic vaccines...." Accordingly, Applicants assert the instant

specification discloses that viral, bacterial and parasitic antigens may be used either alone or together in the claimed methods.

Moreover, Applicants assert that regardless of the pathogen from which the antigen is derived, the methods of the pending claims in fact all have the same mode of operation, the same function and the same effects. Thus, irrespective of the actual antigen employed, the combination of the antigen and the adjuvant can be administered to the target animal using similar methodologies in order to potentiate an immune response against the antigen in the animal. As such, the methods of the currently pending claims all have the same mode of operation regardless of the pathogen from which the antigen was derived. Similarly, for all antigens, the methods of currently pending claims have the same objective, namely, to potentiate an immune response against the antigen, and therefore all have the same function, as well as producing the same end effect, *i.e.* the potentiation of an immune response against the antigen in the recipient animal.

For the reasons set forth above, Applicants assert that alleged Species i-iii are related and, therefore, a search of the prior art with respect to all three alleged species of antigen can be easily conducted and does not represent any serious burden on the Examiner.

In summary, Applicants assert that the Examiner has not *prima facie* established that the currently pending claims meet the criteria as set forth in MPEP § 803 for proper requirement for restriction. Solely in order to expedite prosecution of the instant application, however, Applicants have elected alleged Invention I (Claims 20-39 and 42). For the reasons outlined above, Applicants maintain that alleged Invention I should be defined as related to a method of potentiating an immune response in a mammal and, therefore, assert that, should the above restriction be made final, elected Invention I should encompass all claims directed to a method of potentiating an immune response in a mammal comprising administering an antigen and an effective amount of an adjuvant comprising

PapMV or a PapMV virus-like particle. Applicants further elect alleged Species i drawn to viral antigen.

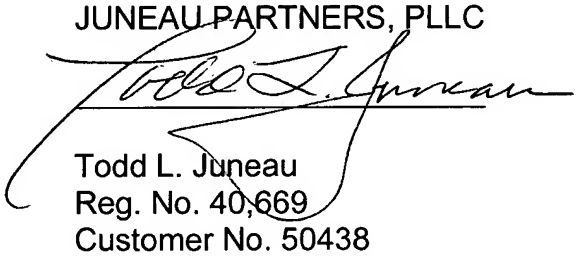
CONCLUSION

In view of the foregoing, Applicants respectfully request the Examiner to reconsider and withdraw the restriction requirement, and to examine all of the claims pending in this application.

If the Examiner has any questions or wishes to discuss this matter, the Examiner is welcomed to telephone the undersigned attorney.

Respectfully submitted,

JUNEAU PARTNERS, PLLC



Date: October 12, 2005

JUNEAU PARTNERS, PLLC
2506 Clay Street
Alexandria, VA 22302
Tel: (703) 836-7026

Todd L. Juneau
Reg. No. 40,669
Customer No. 50438